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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,484	02/18/2004	Rafail Zubok	SPINE 3.0-455 CIP CONT V	3112
51640 SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090	7590 02/17/2009		<div>EXAMINER</div> <div>WOODALL, NICHOLAS W</div>	
			<div>ART UNIT</div> <div>3775</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>02/17/2009</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/781,484

**Applicant(s)**

ZUBOK ET AL.

**Examiner**

Nicholas Woodall

**Art Unit**

3775

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 23 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 33-38 is/are rejected.
- 7) ☒ Claim(s) 23 and 25-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This action is in response to applicant's amendment received on 11/24/2008.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

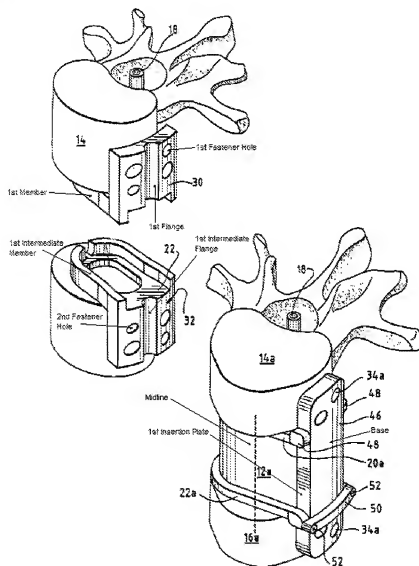
3. Claims 1 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Songer (U.S. Patent 6,395,030).

Songer discloses a device comprising a first member, a first intermediate member, and a first insertion plate (see Figure 1 below). The first member includes a first vertebral contact surface, a first articulation surface, and a first flange including a first through hole capable of receiving a bone screw and a first fastener hole. The first intermediate member includes a first intermediate vertebral contact surface capable of contacting an endplate of an intermediate vertebral bone adjacent to the first vertebral bone and a first intermediate flange entirely offset to one side of a midline of the device, i.e. the midline splitting the device medial/lateral placing the flange on one side of the device, including a second fastener hole offset from the first fastener hole of the first member. The first insertion plate is capable of engaging the first member and the first intermediate member, wherein the first fastener hole and the second fastener hole are sized and positioned to receive at least one fastener to couple the first insertion plate to the first member and the first intermediate member, wherein the first insertion plate is

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capable of orienting the first member and the first intermediate member for simultaneous insertion into an intervertebral disc space defined by the first vertebral bone and the first intermediate vertebral bone.

Figure 1



***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Songer (U.S. Patent 6,395,030).

Songer discloses the invention as discussed above wherein the first insertion plate is capable of orienting the fastener holes of the first member and the first intermediate member to have a configuration substantially similar to that of a spinal fusion plate, wherein the first insertion plate is capable of engaging and orienting the first member and the first intermediate member for simultaneous insertion into the first intervertebral disc space. Songer further discloses a device wherein the first insertion plate includes a base, a first mounting element, such as the screw going into the first fastener hole, capable of engaging the first member, and a first intermediate mounting element, such as the screw going through the second fastener hole, capable of engaging the first intermediate member, wherein the first mounting element and the first intermediate mounting element are offset in opposite directions with respect to one another relative to a longitudinal axis substantially parallel to the longitudinal axis of the spine. Songer fails to disclose the device further comprising a second member, a second intermediate member, and a second insertion plate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the

device of Songer further comprising a second member, a second intermediate member, and a second installation plate, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

***Allowable Subject Matter***

6. Claims 23 and 25-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

7. Applicant's arguments with respect to claims 1-6, 23, and 25-38 have been considered but are moot in view of the new ground(s) of rejection. The applicant's argument that the Songer reference does not disclose a device wherein the flange is on one side of a medial line of the device is not persuasive. The claims are silent regarding to which midline the flange's location is based upon. Therefore, any midline can be interpreted as meeting the requirement as long as the flange is on one side of the midline, which the examiner has shown the device discloses the limitations of the claims if the medial/lateral midline is used as discussed above. The applicant's argument that the Songer reference does not disclose an insertion plate that connects to the plates prior to insertion is not persuasive. These limitations are not required by the claims. All that is required is that the insertion plates are capable of engaging the elements. The applicant's argument that claim 33 includes all the limitations of claims 1 and 23 is not persuasive. Claim 23 requires the articulation surfaces to allow for articulation of the

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vertebral bodies, but claim 33 does not require this limitation and therefore does not require all the limitations of the claim. Since claim 33 only requires a named surface, Songer clearly discloses an articulation surface since the surface is not required to do anything in the claim. Therefore, claims 33-38 have been rejected using the Songer reference as discussed above. Furthermore, if claim 33 did include all the limitations of claims 1 and 23, then claim 33 would be a duplicate claims and therefore not allowable. The examiner has provided new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

#### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/  
Examiner, Art Unit 3775  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733